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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,149	11/01/2000	William F. Swain	APF 34.20	4573

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/705,149	SWAIN ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) *1-14 and 35-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/02/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-51 are pending.

RCE

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/03/2003 has been entered. An Action on RCE follows:

Election/Restrictions

1. Applicant's election with traverse of Group II, claims 15-25 in the reply filed on 07/02,2004 is acknowledged. The traversal is on the ground(s) that Groups III and Group IV should be rejoined together because in the previous Office Action dated April 25, 2002, these groups were kindly rejoined by the examiner. Applicants' argument has been fully considered, groups III and IV, claims 15-34 are rejoined.

Response to Amendment

2. This is a response to the amendment, paper No. 16, filed 12/03/03. Claims 19, 21, 28, 30 have been amended. Claims 1-51 are pending. Claims 15-34 are considered before the examiner.

3. Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 15-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 15, 19 and 28 are still rejected for using a relative term of "derived". Applicants respectfully submit that the term derived" should be given its ordinary meaning to one of skill in the art and that applicants have described the term consistently in the specification as a sequence is derived or obtained from a molecule if it has the same or substantially the same base pair sequence as a region of the source molecule, its CDNA, complement thereof or if it displays sequence identity as further described in the specification. (See page 15, 11. 1-4). Applicants submit that the term is sufficiently clear and definite that one of ordinary skill in the art would understand the metes and bounds of the claim. As such, applicants respectfully request that the rejection be withdrawn.

Applicants' argument has respectfully considered; however, it is not found persuasive because the limitation described in the specification cannot read into the claim.See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicants are suggested to amend claim by using more defined language to overcome the rejection.

Claim Rejections - 35 USC § 112

7. Claims 15-34 are still rejected under 35 U.S.C. 112, first paragraph on the same ground as stated in the previous Office Action, because the specification, while being enabling for a method of using a gold core carrier coated with a cosmid DNA vector that carries a large fragment of HSV to induce an immune response in mice, does not reasonably provide enablement for a method of using any or all metal beads as a core carrier to carries any or all large DNA fragment with at least 5 kb in size from any or all one or more pathogen of viruses in any or all vector to induce an immune response in animal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

8. Applicants traverse the rejection and submit that the specification discloses and enables more than the narrow HSV glycoprotein D to induce immune response in an animal. (See Examples at page 41-49). The Examples describe the assembly of numerous different antigen

constructs that have been assembled according to the claimed invention and then demonstrate that these constructs have the recited features in working, art-recognized animal model systems. Several other viral pathogens have also been motioned in the specification.

9. Applicants' argument has been respectfully considered. The examiner notes that the Example 1 teach six different cosmid constructs were made, each containing different EcoRl restriction genomic fragments from HSV-2, which were administered to mice in an art-recognized model and established to induce the desired immune response. (See page 46, 11. 6-16). Example 2 teaches a plasmid construct that is able to contain 8500bp of HSV-2 DNA (including genomic sequences encoding glycoprotein B protein antigen). However, the scope of claims read on any or all vector and plasmid that is carries any or all fragment of a viral pathogen. The specification teaches that a fragment can be any molecule if it has the same or substantially the same base pair sequence as a region of the source molecule, its CDNA, complement thereof or if it displays sequence identity. Therefore, the scope of the claimed fragment reads on any virus cDNA, such as a HCV or HIV with a single base mutation. This is very unpredictable because administration of a mutated HIV or HCV viral genome with couple of nucleic acid mutation into a host can cause an active infection. According to the state of art, not all plasmid or vector can carries more than 5 kb insert. For example, a recombinant adeno-associated virus vector is not suitable for packaging an inserted DNA fragment over 5kb as taught by Flotte et al. (Gene Therapy 1995, Vol. 2, pp. 357-362).

10. Regarding to using any or metal as an DNA vaccine core carrier, Applicants also argue that the specification describes several metals, besides gold, that can be used in accordance with this invention (See page 34 11. 4-5). The specification teaches tungsten, gold, platinum, and iridium as examples of metals that can be used in accordance with this invention. (See page 34 11. 4-5). Those of ordinary skill in the art would know which other metals can also be used in accordance with this invention. It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. In re Vaeck, 947 F.2d 488, 496 ('Fed. Cir. 1991).

11. Applicants' argument has been respectfully considered, however, it is not persuasive because the scope of claims read broadly on any or all metal. The state of art teaches that not all metal can be used as a antigen carrier protein because a lot of metals are toxic as evidenced by de

Boer JG et al. (Carcinogenesis. 1992, Vol. 13, pp.15-7) and Reid et al. (Environ Health Perspect. 1994 Sep;102 Suppl 3:57-61). Boer et al. teach that Platinum-based compounds such as cisplatin and carboplatin are currently used for the treatment of a variety of solid tumors. Their primary mode of action involves the production of cross-links in DNA. These compounds induce mutations in bacterial as well as in mammalian cells (see abstract). Reid et al. teach that Fe2+, Cu2+, and Ni2+ are all carcinogenesis for mammalian cells (See abstract).

12. Considering the limited teaching from the specification does not support that any or all DNA fragments over 5 kb from any or all one or more than one viruses can be carried by any or all vector or plasmid, and are coated onto any or all metal, the rejection is therefore, maintained.

New Grounds of Rejections

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

14. Claims 15-19, 22-28, 31-34 are rejected under 35 U.S.C. 102(a) as being anticipated by Suter et al. (Vaccine 1999, Vol. 96, No. 22, pp. 12697-13702).

15. Suter et al. teach a method for eliciting an immune response in mice comprising providing a gold particle (1 μM) adsorbed with a mutated HSV1 DNA. The mutated HSV-1 DNA is a 152 kb HSV-1 genome with its cleavage/packaging single (pac) excluded (fHSV∇pac), and is packaged in the E coli F plasmid. The coated gold beads comprising 750 ng DNA are injected into mice with gene gun during the primary and boost immunizations. The HSV-1 specific humoral and cellular CTL immune responses are induced (See pages 12699-12700,especially Figs. 2-3 and Table 1). A repeated immunization with this approach results in a

clear protection of mice challenged with wild type HSV-1 (See page 12710, especially Fig. 5). Therefore, the claims are anticipated by the cited reference.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 15-20, 22-29, and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suter et al. (Vaccine 1999, Vol. 96, No. 22, pp. 12697-13702) in view of Hilliard et al. (Arch Virol. 1989, Vol. 109, No. 1-2, pp. 83-102).

18. Claimed invention are drawn to a method for eliciting an immune response comprising constructing a DNA plasmid comprising a virus genomic DNA fragment, coating the DNA plasmid onto a gold particle, and delivering a sufficient amount of DNA coated Gold beads into a mammal. The genomic DNA is preferably a fragment of HSV1 or HSV2 that does not contain a heterologous promoter and is between 5 kb to 25 kb in size. The gold particle is about 0.5-5.0 μM in diameter.

19. Suter et al. teach a method for eliciting an immune response in mice comprising providing a gold particle (1 μM) adsorbed with a HSV1 DNA. The HSV-1 DNA is a 152 kb HSV-1 genome with its cleavage/packaging single (pac) excluded (fHSV▽pac), which is packaged in the E coli F plasmid. The coated gold beads comprising 750 ng DNA are injected into mice with gene gun in the primary and boost immunizations, which induces a HSV-1 specific humoral and cellular CTL immune responses (See pages 12699-12700,especially Figs. 2-3 and Table 1). A repeated immunization results in a clear protection of mice from the challenge with wild type HSV-1 (See page 12710, especially Fig. 5). Suter et al. do not teach to use HSV-2 genomic fragment.

20. Hilliard et al. teach that antigenically, HSV 1 and HSV 2 were most closely related to each other in structures and functions. Cross-hybridization between simian and human herpesvirus genomes demonstrated that extensive homology exists between each of the simian viruses and both HSV1 and HSV 2. Viral polypeptides bearing common antigenic determinants were identified by immune precipitation of infected cell polypeptides and by immunoblotting (See entire document, especially the sequence comparison on page XX).

21. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was filled to be motivated by the recited reference of Suter et al. to constructing a DNA vaccine with HSV-2 genomic fragment instead of HSV-1 fragment to see a similar immune response. As there are no unexpected results have been provided, hence the claimed invention as a whole is prima facie obvious absence unexpected results.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li
August 18, 2004

James C. Housel 8/23/04
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